UNITED STATES DEPARTMENT OF COMMERCE
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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/337,746	06/22/99	GLENN G	PM-254811

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EXAMINER	
TUNG, M	
ART UNIT	**PAPER NUMBER**
1644	14

DATE MAILED: 12/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/337,746	GLENN ET AL.	
	Examiner	Art Unit	
	Mary B Tung, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *04 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☒ Other: *Fax Coversheet* .

DETAILED ACTION

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

I. Restriction to one of the following inventions is required under *35 U.S.C. § 121:*

I. Claims 1-42, 45 and 47-69 drawn to a method for transcutaneous immunization using an antigen, classified in class 424, subclass 184.1.

II. Claims 1, 43, 44 and 46, drawn to a method for transcutaneous immunization, using a nucleic acid, classified in class 514, subclass 44.

1. The inventions are distinct, each from the other because of the following reasons:

2. Groups I and II and are unique methods. They differ with respect to ingredients, process steps and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classifications, and because a non-patent literature and/or sequence search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

4. Should Applicants traverse on the ground that the members of the groups are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

NOTE: Claim 1 is recited in both groups and will be examined only to the extent of the elected invention.

5. If Group I is elected, the applicant may elect, the applicant is further required under 35 U.S.C. 121:

> To elect a **specific antigen:** if a pathogen is elected, to further elect: a bacterium, virus, fungus or parasite, as recited in claims 29-32 and 38-40, **or** an autoantigen, as recited in claim 45, **or** a tumor antigen, as recited in claims 48-50, **or** an allergen, as recited in claims 51 and 52, **or** if an ADP-ribosylating exotoxin is elected, to further elect: cholera, diptheria, pertussis, and tatanus, as recited in claim 54 **or** influenza virus nucleoprotein, **or** influenza virus hemagglutinin, **or** *Hemophilus influenza* B polysaccharide **or** *Escherichia* coli colonization factor CS6, as recited in claim 56.

6. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Should Applicants traverse on the ground that the members of the species are not patentable distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentavble over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP ' 809.02(a).

9. The following claim(s) are generic: Claim 1 is generic with respect to the elected invention.

10. The species are distinct each from the other for the following reasons:

> The recited antigens, have different biochemical characteristics, structure and functions.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with *37 C.F.R. ' 1.48(b)* if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under *37 C.F.R. ' 1.48(b)* and by the fee required under *37 C.F.R. ' 1.17(h)*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary B. Tung, Ph.D. whose telephone number is 703-308-9344. The examiner can normally be reached on Tuesdays - Fridays 8:30am - 6:00pm, and on alternating Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Mary B. Tung, Ph.D.
Examiner
Art Unit 1644

mbt
November 30, 2000

MARY BETH
PATENT